

Remarks and Arguments

Claims 29-67 were pending in the application. Claim 29 has been amended. Claims 29-67 remain for examination.

Examiner Interview Summary

On December 5, 2006, the Examiner mailed an Interview Summary regarding the telephonic conference held December 1, 2006. Applicant is in substantial agreement with the description of the substance of the interview set forth in the Examiner's summary.

Applicant submits herewith a copy of the exhibit presented at the interview and referenced in the Examiner's Interview Summary.

Independent claim 29 was discussed and it was agreed that Applicant would insert "formation of" in front of the word "osteodentin" in claim 29. Applicant has amended claim 29 accordingly.

In the final office action, claims 29-67 were rejected under 35 U.S.C. § 102(e) as being anticipated by Cerny et al. U.S. Patent 6,300,062. The Examiner made certain assumptions about Cerny's described method of repairing a lesion in a tooth.

At the interview, there was extensive discussion about Cerny et al. The Examiner was directed to an Internet site provided by Applicant (<http://en.wikipedia.org/wiki/Image:ToothSection.jpg> (copy enclosed)) where one can clearly see how deeply the pulp is hidden inside the tooth, which supports Applicant's distinction over Cerny et al. The Examiner's summary of the following discussion was substantially accurate and complete in stating:

"Applicants describe how Cerny et al. is distinguished from the pending claims because the reference does not disclose the exposure of vital dental pulp as is currently claimed in claim 29;"

Applicants "used the exhibit image to describe the depth of vital dental pulp;"

"Applicants cite col. 15, line 37 onwards of U.S. Patent '062 to support the position that Cerny et al. does not

contemplate exposure of vital dental pulp tissue" and "that [Cerny's] mineralization is distinguished from [Applicant's claimed] regeneration of secondary dentin or formation of reparative dentin or formation of osteodentin."

The Examiner then agreed to consider the submission of a Declaration from the Cerny et al. inventors (same Assignee) that would state that the Cerny et al. patent "is not directed to promoting regeneration of secondary dentin or formation of reparative dentin or formation of osteodentin in a mammal." (Examiner's Interview Summary Record, page 3).

Applicants submit herewith a Declaration by Dr. Ivan Slaby, the second named inventor of the Cerny et al. patent. The Declaration includes a description of Dr. Slaby's background, and a discussion of the Cerny et al. patent disclosure consistent with the above-noted distinctions from the Interview Summary Record. Based on this evidence, Applicant respectfully submits that the Cerny et al. patent fails to teach or suggest the subject matter of Applicant's amended independent claim 29.

In the final office action, the Examiner objected to use of the term "derivatives" on the grounds it was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) at the time the application was filed, had possession of the claimed invention. The Examiner asserted that "the specification does not describe what structural modifications for the recited enamel matrix proteins in the enamel matrix substance can be made, which will still produce a composition capable of mineralizing dentin. No structure to function correlation is disclosed for the respective enamel proteins." (Office Action, page 4 and 6). The Examiner further asserted that "claims 38 and 39 are broadly generic to all possible derivatives of enamel substances" and "...the possible variations are enormous." (*Id.* at page 7). The Examiner further asserted that "the specification is devoid of any derivatives thereof that qualify for the functional characteristics claimed." (*Id.* at page 7).

Applicant respectfully asserts that Applicant's limited use of the term derivatives is proper and there is a clear disclosure in the specification of what is meant, including:

a) the term "enamel matrix derivative" has previously been described in the patent literature and is thus familiar to persons of ordinary skill in the art (see e.g., the

referenced public patents identified in paragraphs [0003, 0094 and 0104] of the specification);

b) an extensive definition of "Enamel Matrix, Enamel Matrix Derivatives and Enamel Matrix Proteins" is set forth in paragraphs [0092-0114] of the specification, which includes beginning at paragraph [0095] the specific disclosure:

In the present context, enamel matrix derivatives are derivatives of enamel matrix which include one or several of enamel matrix proteins or parts of such proteins, produced naturally by alternate splicing or processing or by either enzymatic or chemical cleavage of a natural length protein, or by synthesis of polypeptides in vitro or in vivo (recombinant DNA methods or cultivation of diploid cells). Enamel matrix protein derivatives also include enamel matrix related polypeptides or proteins. The polypeptides or proteins may be bound to a suitable biodegradable carrier molecule, such as polyamino acids or polysaccharides, or combinations thereof. Furthermore, the term enamel matrix derivatives also encompasses synthetic analogous substances.

and is followed by a detailed description with examples of such polypeptides or proteins, their molecular weights, relative weight fraction in the composition, and amino acid sequences [0096-0114];

c) a description of the "Physico-Chemical Properties of Enamel Matrix, Enamel Matrix Derivatives and Enamel Matrix Proteins" beginning at paragraph [0115] and reciting in the following paragraph [00116]:

In general the enamel matrix, enamel matrix derivatives and enamel matrix proteins are hydrophobic substances, i.e., less soluble in water especially at increased temperatures. In general, these proteins are soluble at non-physiological pH values and at a low temperature such as about 4-20° C.,

while they will aggregate and precipitate at body temperature (35-37°C.) and neutral pH.

d) identification of a commercially available enamel matrix derivative product, e.g., EMDOGAIN® [0098]; and

e) an Experimental Section with 15 examples illustrating preparation and use of an enamel matrix derivative [0218-0424].

Thus, Applicant respectfully asserts that based on the previously published patent literature, commercially available product, and Applicant's extensive specification, the skilled person has a clear understanding of what is meant by "derivatives" of the recited group of active enamel compounds.

Reconsideration and allowance is respectfully requested.

Information Disclosure Statement

Applicant submits herewith an Information Disclosure Statement with the correct pages 150-196 of the A.R. Ten Cate reference.

RECONSIDERATION

It is believed that all claims of the present application are now in condition for allowance.

Reconsideration of this application is respectfully requested. If the Examiner believes that a teleconference would expedite prosecution of the present application the Examiner is invited to call the Applicant's undersigned attorney at the Examiner's earliest convenience.

Any amendments or cancellation or submissions with respect to the claims herein is made without prejudice and is not an admission that said canceled or amended or otherwise affected subject matter is not patentable. Applicant reserves the right to pursue canceled or amended subject matter in one or more continuation, divisional or continuation-in-part applications.

To the extent that Applicant has not addressed one or more assertions of the Examiner because the foregoing response is sufficient, this is not an admission by Applicant as to the accuracy of such assertions.

\$180.00 under 37 CFR §1.17(p) is enclosed, *and*

- ☐ each item of information contained in this statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement, or
- ☐ no item of information contained in this statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in this statement was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

Payment

- ☐ A check in the amount of the submission fee is enclosed.
- ☒ Charge Account No. 02-3038 in the amount of the submission fee.

Authorization to Charge Additional Fees

- ☒ The Commissioner is hereby authorized to charge any additional fees under 37 C.F.R. §1.16 and §1.17 required by the attached paper and during the entire pendency of this application to Account No. 02-3038.

Respectfully submitted,

/therese hendricks/

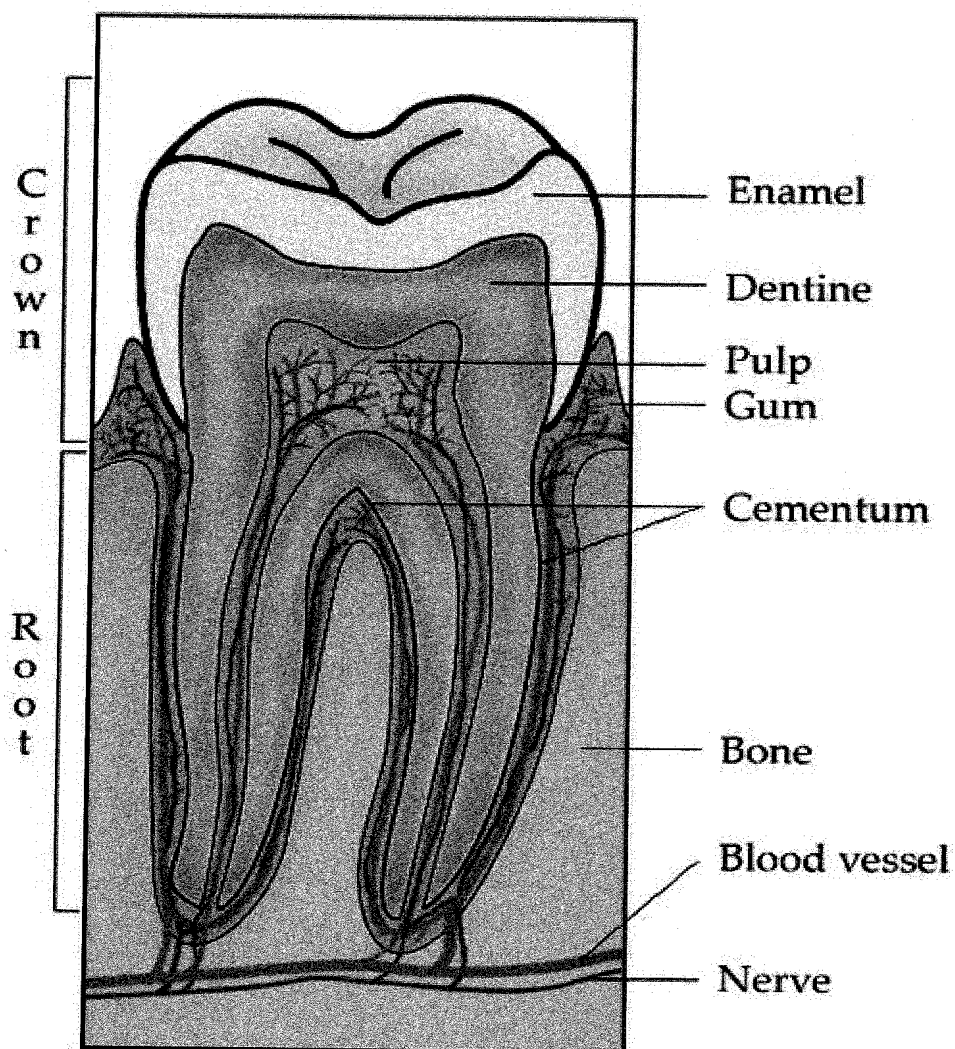
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